

### Remarks

This Amendment and Response is in reply to the Office Action mailed August 4, 2003 in the subject application.

Claims 1-16 are pending, with claim 16 being newly added.

#### **Rejections under 35 USC 112, paragraph 2**

Claims 1-15 have been rejected in the Office Action for indefiniteness for failure to particularly point out and distinctly claim the subject matter Applicants consider to be their invention.

As indicated above, several of these claims have been amended along the lines suggested by the examiner, though Applicants disagree that the claims as originally presented were indefinite. Other clarifying amendments were made to the claims. No new subject matter was introduced by any of these amendments.

Applicants particularly note that the expression "bPTH/80" would be clear to those skilled in the art, even if the examiner was confused by the terminology, to mean baseline PTH divided by 80, *not* baseline PTH equals 80, as the examiner has suggested.

With respect to the examiner's rejection of claims 11, 12 and 14, the Office Action incorrectly states that these claims "depend directly or indirectly from claim 7." A careful review of these claims establishes that these are independent claims; they do not in fact depend from claim 7 or any other claim. Hence the rationale offered in the Office Action for the indefiniteness rejection does not make sense as to these claims. Therefore, this rejection is improper and should be withdrawn.

#### **Prior Art Rejections**

##### *A. Cummings*

Claims 1 and 2 stand rejected as anticipated by Cummings (US 5891868). The Office Action states that Cummings teaches the various steps of Applicants' claimed invention.

Applicants strongly disagree.

A careful reading of the claims in the subject application indicates that the Cummings patent is irrelevant to the patentability of Applicants' invention. Each of the independent claims (as amended above) makes this plain. For example, claim 1 begins with a preamble which states:

1. "A method of determining the initial dose of a vitamin D compound for the treatment of secondary hyperparathyroidism and renal osteodystrophy without increasing the incidence of hypercalcemia..."

No one skilled in the art would read Cummings to teach anything about a method for determining the initial dose of a Vitamin D compound. Instead, it is absolutely clear that Cummings relates to "methods for treating physical

conditions resulting from postmenopausal estrogen decline in a postmenopausal subject." (See the abstract). Moreover, Column 4, lines 1-10 of Cummings state:

"The present inventors have also unexpectedly discovered that the treatment of physical conditions resulting from estrogen decline can be affected by ultra low doses of estrogen without the need for administration of progestin."

Cummings does nothing more than make reference to following serum Vitamin D in the patients who were given multi vitamins containing Vitamin d in order to identify risks bone fractures. The examiner's attention is drawn to Cummings at column 3, lines 35-45, and especially lines 43-45 which state:

"In addition, low serum levels of 1,25 (OH)<sub>2</sub> Vitamin D levels also leads to increased risk of hip fractures."

With respect to other independent claims, Applicants also disagree that Cummings provides any relevant teaching for "treatments of secondary hyperparathyroidism and renal dystrophy without increasing the incidence of hypercalcemia" (claim 6), method of treating elevated PTH in a patient commencing treatment for end stage renal disease" (claim 7), "method of treating a patient for end stage renal disease using a vitamin D therapy (claim 10).

The rejection of Applicants' claimed invention over Cummings is improper and should be withdrawn.

*Cummings/Knutson*

Claims 1-15 stand rejected as obvious over the combined teachings of Cummings and Knutson (U.S. 5602116).

As indicated above, Cummings completely fails to teach any methods relevant to Applicants' claimed invention. Applicants further disagree with other statements in the Office Action, as follows.

The office action states that "Cummings discloses that low serum level of vitamin D compounds leads to bone loss disorders (column 2, lines 43-45). In fact, these lines do not state this, but instead state the following:

"Post menopausal subject" refers to women in the period of life after menopause. Subjects afflicted with post-menopausal symptoms include women after menopause who exhibit any of the foregoing physical conditions after menopause, and particularly women after menopause who have exhibited decreased bone mineral density, in the vertebrae, hip or other site or who have experienced wither vertebral or hip fracture."

The statement in the Office Action clearly is not factually based upon the cited passage.

With respect to the proposed combination of Cummings and Knutson, Applicants note that even if the examiner has correctly analyzed the teachings of Knutson, Knutson does not compensate for the deficiencies pointed out above with respect to Cummings.

Thus, the rejection is insufficient to render Applicants' invention as presently claimed obvious. The rejection should therefore be withdrawn.


**Conclusion**

Applicants respectfully submit that the subject application is in condition for allowance and prompt allowance thereof is respectfully requested.

The examiner is urged to telephone the undersigned at 847 937 4558 to facilitate resolution of any remaining issues so that the subject application can be processed for allowance promptly.

Respectfully submitted,  
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